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GAIN Report

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CRISPR and other NBT's classified as GMO's

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Biotechnology and Other New Production
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Report Highlights:

A legal analysis commissioned by the German Federal Agency for Nature Conservation concludes that CRISPR and other new breeding techniques fall under the European Directive for GMOs.

General Information:

A legal analysis released in late October and commissioned by the German Federal Agency for Nature Conservation addressed questions regarding CRISPR and other new plant breeding techniques. Bottom line of the legal analysis is that these new breeding techniques fall under the scope of Annex I A Part 1 No. 1 of Directive 2001/18/EC (Directive for the deliberate release of genetically modified organisms). This classification is based on the analysis of not only the wording and history of the Directive, but also on systematic considerations. The legal analysis was prepared by Professor Dr. Tade Matthias Spranger, Faculty of Law at the University of Bonn.

Summary of the results

The legal analysis comes to the conclusion that for the regulation of new breeding techniques it should be of no importance that mutations also occur naturally. As this represents a target-oriented point mutation, Annex I A Part 1 No. 1 has to be applied to the relevant new breeding techniques.

Of particular relevance in this context is the fact that the Directive makes use of an indicative list to assure the (future) applicability of the regulatory framework regarding techniques in question. Also, the legal analysis points to the term mutagenesis in Annex I B which explicitly covers conventional mutagenesis. The report found that, considering the insufficient safety record of the new technologies, an application of Annex I B would not be possible.

According to the legal analysis, the described legal framework corresponds with the precautionary principle which characterizes the law on deliberate release in a way that is stated in the "Communication from the Commission of 2 February 2000 on the precautionary principle". The conclusion of the legal analysis is that the application of Annex I A Part 1 to these new technologies guarantees the realization of the European approach to regulate processes which has a significant impact on the entire European law on genetic technology.

The new breeding techniques reviewed by the legal analysis include Zinc Finger Nucleas Technology, the Oligonucleotide Directed Mutagenesis (ODM), the Transcription Activator-Like Effector Nucleases and the use of Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR).

Please see full text of legal analysis for more information:

http://bfn.de/fileadmin/BfN/agrogentchnik/Dokumente/Legal_analysis_of_genome_editing_technologies.pdf

Background Information

The German Federal Agency for Nature Conservation (BfN) is the German government's scientific authority with responsibility for national and international nature conservation. BfN is one of the government's departmental research agencies and reports to the German Environment Ministry. The Agency provides the German Environment Ministry with professional and scientific assistance in all nature conservation and land management issues and in international cooperation activities.

The legal analysis could indicate the position of the German Environment Ministry regarding new breeding techniques. The German Environment Ministry and its Minister Barbara Hendricks are critical

towards agricultural biotechnology.

The Federal Ministry for Food and Agriculture traditionally has the lead when it comes to the assessment of biotechnology but other ministries, like the Federal Environment Ministry, the Federal Ministry of Justice and the Federal Ministry for Economy, also need to be consulted. In the past, the German Government has usually abstained at votes for the approval of biotech traits in Brussels when it could not form a position.

The Federal Ministry for Food and Agriculture has indicated its position in June 2015 when the Federal Office of Consumer Protection and Food Safety (BVL) finally classified a herbicide-resistant rapeseed that was produced using ODM as non GMO. The position by the Federal Ministry for Food and Agriculture is leaning towards a case-by-case approach which could provide access to innovations in the future.

For more information please see following GAIN reports:

[Objection against CIBUS rapeseed rejected](#)

[Agricultural Biotechnology Annual 2015](#)